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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/680,557	MCGRATH, KEVIN P.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 24 April 2006.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.
 4a) Of the above claim(s) 1-12,14-16 and 26-38 is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) 13 and 17-25 is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a)☐ All b)☐ Some * c)☐ None of:
  1.☐ Certified copies of the priority documents have been received.
  2.☐ Certified copies of the priority documents have been received in Application No. _____.
  3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 4/24/06;8/11/05;8/6/05;1/12/04.
4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group V, claims 13 and 17-24, the species being SEQ ID NO:1, in the reply filed on April 24, 2006 is acknowledged. The traversal is on the ground(s) that Applicant asserts that a search of all of the inventions would not be an undue burden, and that Applicant asserts that a search for SEQ ID NO:2 would overlap with the search of SEQ ID NO:1.

This is not found persuasive because while SEQ ID NO:1 may be an epitope of SEQ ID NO:2, a search for cyclic SEQ ID NO:1 is not commensurate in scope with a search for cyclic SEQ ID NO:2. Commensurate with formula (I), SEQ ID NO:1 is cyclo(1-9)[CTKSIPPIC], while SEQ ID NO:2 is cyclo(1-14)[GRCTKSIPPICFPD]. The cyclic structures are searched based upon their unique structures, such that a search of one structure would not necessarily lead to the discovery of the other.

Claim 25 has been rejoined with Group V to the extent that it reads upon the elected invention, formula (I), SEQ ID NO:1 because in the broadest reasonable interpretation the art applied below identifies a cyclic peptide comprising any of SEQ ID NOs:1-3 where SEQ ID NO:1 is cyclic.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-12, 14-16 and 26-38 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 24, 2006.

Claims 13 and 17-25 have been examined on the merits.

Information Disclosure Statement

Applicant's IDS submissions of April 24, 2006, August 11, 2005, August 5, 2005 and January 12, 2004 are acknowledged.

References not in English have been considered to the extent of the provided English abstract and/or statement of relevance in the specification.

Abstract

The abstract of the disclosure is objected to because it is not fully descriptive of the instant invention, as it is of a broader scope than the instantly claimed invention(s). Correction is required. See MPEP § 608.01(b).

Specification

The disclosure is objected to because of the following informalities:

Page 36, lines 26-29 recites, "Under no circumstances may the patent be interpreted to be limited by any statement made by any examiner or any other official or employee of the Patent and Trademark Office unless such statement is specifically and without qualification or reservation expressly adopted in a responsive writing by Applicants." Respectfully, this statement is inappropriate in an Application/Patent, as it is in direct opposition to the Rules for US Patent prosecution, including 37 CFR § 1.104. For example, if Applicant were not to respond to the instant office action within the allowable period, the Application would be abandoned for failure to respond, without Applicant's express adoption in a responsive writing.

The definition of "a," "an," and "the," as including the plural (page 36, lines 21-23), is repugnant to the art, in view of Applicant's use of the terms. For example, "a compound of generic formula (I)," is widely accepted in the art as referring to a single compound, and is significantly different in scope than recitation of, "one or more compounds of formula (I)," which is acceptable for describing one or more compounds.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on Page 9. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The use of the trademark(s), e.g., page 30, line 11, has/have been noted in this application. A trademark should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant should capitalize each letter of the word or include a proper trademark symbol, such as ™ or ® following the word. Further, language such as "the product X (a descriptive name) commonly known as Y (trademark)" is impermissible, since such language does not bring out the fact that the latter is a trademark. Language such as "the product X (a descriptive name) sold under the trademark Y" is permissible. See MPEP § 608.01 (v).

Appropriate correction is required.

Additionally, the lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claims 13 and 17-25 are objected to because of the following informalities:

Claims 13 and 25 recite, "a cyclic peptide", wherein the use of 'a' to embrace more than one, is repugnant to the art. If Applicant intends the claim to embrace more than a single species, the claims must recite as such, e.g. 'one or more', as 'a' is widely used in the art to refer to a single compound, and never to a group.

Claims 17-24 are objected to for depending from nonelected inventions which are withdrawn from consideration.

Assuming *arguendo* that 'a' is given the plain meaning of the singular, Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 19 is of a broader scope than claim 13, as claim 19 is administering one or more peptides.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13 and 17-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of skin irritation on a mammal with peptides having cyclo(SEQ ID NO:1), does not reasonably provide enablement for prevention of skin irritation with any peptide or for treating with all other cyclic peptides having a sequence of formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (Wands, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (Wands, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to treating or preventing skin irritation on a mammal with administration of a cyclic peptide having an amino acid sequence of formula (I), formula (I) being a cyclopeptide of nine amino acids.

Thus, the claims taken together with the specification imply one could practice this method with any of a myriad of cyclopeptides, so long as the cylcopeptide comprises at least a dipeptide sequence from formula (I).

Please note, the scope of 'a sequence of' is broadly interpreted as fragments, while the scope 'the sequence of' would necessarily require the recited structure.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

With regards to the effect of amino acid substitution in a peptide or protein, the art is unpredictable.

RUDINGER (J. Rudinger. In: Peptide Hormones, JA Parsons, Ed. (1976) 1-7) teaches that, "The significance of particular amino acids and sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study." (Page 6).

MATHISON (US Patent 6,586,403 B1) teaches that "Restriction on the amino acid substitutions that are tolerated in analogues of FEG/feG are described [...] although a theory for the rational substitution of amino acids in to the peptides that permits the prediction of biological activity of specific peptides is not apparent. For example, it is not obvious which aromatic or aliphatic substitutions in position 1 of tri- or dipeptides would possess biological activity in the four assays examined" (column 12, lines 22-30).

SMILEK (D.E. Smilek, *et al.* Proc. Natl. Acad. Sci. USA (1991) 88, pages 9633-9637) teaches that a single amino acid substitution in the myelin basic protein peptide, "confers the capacity to prevent rather than induce EAE even after peptide-specific encephalitogenic T-cells have been activated." (Abstract).

Further, MPEP § 2144.08 states, "The effect of a conservative substitution on protein function depends on the nature of the substitution and its location in the chain. Although at some locations a conservative substitution may be benign, in some proteins only one amino acid is allowed at a given position. For example, the gain or loss of even one methyl group can destabilize the structure if close packing is required in the interior domains. James Darnell *et al.*, *Molecular Cell Biology* 51 (2d ed. 1990)."

MESSER (W.S. Messer, "Vasopressin and Oxytocin", web document updated 4/3/2000; <http://www.neurosci.pharm.utoledo.edu/MBC3320/vasopressin.htm>; 5 pages) that two compounds, vasopressin [cyclo(1-6)CY**I**QNCP**L**G-NH$_2$] and oxytocin [cyclo(1-6)CY**F**QNCP**R**G-NH$_2$] differ by only two amino acids, as indicated, yet they have different functions. Vasopressin (antidiuretic hormone, ADH), "at low doses controls the resorption of water by the distal tubules of the kidneys and regulates the osmotic content of blood… [and at] high doses, ADH causes contraction of arteriles (*sic*) and capillaries, especially those of the coronary vessels, to produce localized increases in blood pressure." (page 1).

Oxytocin, on the other hand, stimulates smooth muscle contraction in the uterus, mammary glands, and the "alveoli and larger sinuses of the mammary glands to make readily available milk" (page 1).

Further, ADH has 2 types of receptors (V1 and V2) found in vascular smooth muscle and the kidney, while oxytocin has one type of receptor found in uterine and mammary smooth muscle.

(5) The relative skill of those in the art:

The relative skill of those in the art is high with regards to peptide synthesis, however the skill in the art is low with regards to prediction of function derived from substitution or modification, as set forth *supra.*

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided prophetic examples of how one would screen the compounds that might work in the instant methods (page 13, line 10 to page 14 line 17, and page 35, line 19 to page 36, line 2) and how one would make compositions with a myriad of additional elements, the additional elements spanning pages 14 to 31, however the specification fails to put forth a single compound that functions within the methods.

Further, the specification sets forth various interpretations on how one would define conservative substitutions and how one would classify an amino acid. For example, Applicant asserts that Cys can be used to impart nonpolarity to a protein (page 9, line 18), however the art generally recognizes that it is a polar amino acid. From the specification, Applicant is teaching that how amino acids are defined is context based. Further, Applicant indicates that Tyr is non-polar (page 11, line 7), where it is widely held in the art that it is polar, and further lists it as both polar and non-polar in Table 2 (page 10).

Additionally, the art provides only treatment of skin irritation with protease inhibitors, being silent to prevention, e.g. ROURKE (WO 99/45974 A1).

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, the high unpredictability and the lack of guidance provided in the specification, one of ordinary skill in could not practice the invention commensurate in scope with the claims without undue experimentation.

Claims 13 and 17-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*. Although all of the factors are considered, only those necessary for a *prima facie* case are discussed.

The instant claims are presented *supra*.

(1) Level of skill and knowledge in the art:

The level of skill and knowledge in the art is low with knowing which particular cyclopeptides will function in the method as instantly claimed.

(2) Partial structure:

The specification sets forth SEQ ID NOs: 1-3, however the specification does not provide sufficient description of cyclopeptides that are embraced by the genus of compounds of formula (I) that will function as instantly claimed, nor does the specification or claims set forth which features of the members of the broad genus are required to inhibit serine proteases listed.

(3) Physical and/or chemical properties and (4) Functional characteristics:

The compounds of the invention must inhibit serine protease activity and be capable of treating/preventing skin irritation.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that the claims are broad generics, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of cyclopeptide, so long as it has at least a dipeptide of SEQ ID NO:1, e.g. a disulfide bridge. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus. While having written description of cyclo(SEQ ID NO:1) and SEQ ID NOs: 2 and 3 having cyclo(SEQ ID NO:1), the specification is void of a sufficient variety of peptides with functional characteristics required to practice the method.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

> The following is a quotation of the second paragraph of 35 U.S.C. 112:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13 and 25 recite 'a cyclic peptide' wherein 'a' is defined to include a plurality, and it is unclear whether the method involves administration of one, or more than one, and thus the claims are indefinite.

Alternatively, assuming *arguendo*, that the 'context' of 'a' in claim 1 is the singular, claim 19 lacks clear antecedent basis, as 'a cyclic peptide' does not provide support for 'a mixture of peptides'. Further, it is unclear how a single cyclic peptide can be 'a mixture of cyclic peptides'.

Claim 13 recites, 'cysteine-like', 'polar', 'basic', 'nonpolar' and 'aliphatic or neutral polar' for the types of amino acids, and it is unclear what is, or is not, within each amino acid group, as the specification sets forth that, "As will be appreciated by those having skill in the art, the above classifications [referring to the groupings] are not absolute." (page 9, lines 10-11). Further stating that, "It is to be understood that Table 2 is for illustrative purposes only and does not purport to be an exhaustive list of amino acid residues that may comprise the peptides described herein." (page 9, lines 20-21).

Claim 21 recites, "is recognized," which is unclear and indefinite, as it is unclear how a protease 'recognizes' anything, as it is not a living creature.

Claims 22 and 23 recite, "can inhibit," however it is unclear from the claims and specification under what conditions the peptide will inhibit one, or more than one, of the recited serine proteases.

Further, claim 23 recites, "â-trypsin" which is unclear because it is not a known serine protease and is not defined in the specification, and thus it is unclear what trypsin form is inhibited in practicing the method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13, 17-23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by SUNFLOWER (Sunflower seeds. George Mateljan Foundation. Web document. <http://www.whfoods.com/genpage.php?tname=foodspice&dbid=57>, Accessed 6/28/2006, published online 8/25/02, 4 pages).

Sunflower teaches eating sunflower seeds as a snack (throughout). With regards to the alleged prevention aspect of the claims, Sunflower anticipates, as anyone who eats sunflower seeds is inherently administering SFTI-1 and practicing the method as claimed.

Claims 13, 17-23 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by CAWTHON (US Patent 6,627,178 B1).

The instant claims are presented *supra.*

Cawthon teaches a method of treating diaper rash via application of a diaper rash system (e.g. claim 17). In looking to the specification, a preferred embodiment of the system comprises a composition that, "has been found to have particularly excellent features in accordance with the invention comprises about 3 percent calendula extract, about 3 percent chamomile extract, about 3 percent comfrey extract, about 5 percent lanolin, about 5 percent beeswax, about 1 percent lavender oil, about 1 percent geranium oil ,about 54 % sunflower seed oil and about 35 percent cyclomethicone, all by weight (column 10, lines 45-52). Sunflower seed oil inherently has SFTI-1 (*see Rourke*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13 and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over ROURKE (WO 99/45974 A1; 1449, 8/5/05) in view of KORSINCZKY (PTO-1449, 8/11/05).

The instant claims are presented *supra.*

Rourke teaches a method for reducing the proteolytic enzyme activity of fecal protease on a portion of the skin in contact with an absorbent article via administration of a protease inhibitor in an absorbent article to the skin of the wearer (e.g. claim 19 or 20). Reducing the enzyme activity is "useful for the treatment of diaper rash," (page 1, lines 5-7) and diaper rash being, "a common form of irritation and inflammation" (page 1, line 8).

Rourke further teaches that the absorbent article protease inhibitor is selected from inhibitors including various trypsin inhibitors such as Bowman Birk inhibitor (e.g. claim 17).

Korsinczky teaches cyclic and acyclic SFTI-1, two peptides having cyclo(SEQ ID NO:1) and comprising SEQ ID NOs: 2 and/or 3 (Figure 1). It is noted that 'acyclic' has SEQ ID NO:1 cyclized through a disulfide bridge, and thus is 'cyclic'.

Korsinczky teaches that SFTI-1, "is small, cyclic, potent and specific for cathepsins G, making a prime candidate for pharmaceutical and agricultural applications." (page 580, 3rd paragraph).

Korsinczky teaches that cyclic SFTI-1 inhibited bovine β-trypsin with a K_i of 0.5 nM, and the acyclic K_i of 12.1 nM. (page 581, *Trypsin inhibition assays*).

Korsinczky teaches that, "SFTI-1 is homologous to the BB class of trypsin inhibitors across a nine-residue loop region, and due to its small size, inhibits only one proteinase at a time... SFTI-1 is the most potent known BB inhibitor and the only one found to be cyclic." (page 580, 1st paragraph).

The difference between that which is instantly claimed, and that which is taught by Rourke, is that while Rourke teaches the method steps, Rourke does not teach use of a cyclic peptide having cyclo(SEQ ID NO:1).

It would have been obvious at the time of the invention to have used SFTI-1, cyclic or acyclic, in the method of Rourke, because SFTI-1 is the most potent BB inhibitor.

One would have been motivated to use SFTI-1 in the method of Rourke in order to obtain the benefits of using the most potent BB inihibitor known, e.g. using a more effective inhibitor to reduce the amount of product applied.

One would have had a reasonable expectation for success in practicing the instant method with SFTI-1, as Korsinczky teaches that it is a prime candidate for pharmaceutical use and it is taught to be the most potent BB inhibitor and Rourke teaches that any protease inhibitor can be used in the practice of the method.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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